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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Toni-Junell Herbert
Reed Smith LLP
1301 K Street, N.W.
Suite 1100-East Tower
Washington, DC 20005-3373

EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,527	SCHAEFER ET AL.	
	Examiner	Art Unit	
	Lora E Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-66* is/are pending in the application.

4a) Of the above claim(s) *45-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/10/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 10/28/04 is acknowledged. The traversal is on the ground(s) that Groups I-III are united by a special technical feature, namely the product of Group I, and that Group II is not independent from Group I.

Group I is drawn to a biological joint construct comprising a biocompatible carrier material, cartilaginous tissue and osseous tissue, characterized in that one surface of the construct consists of cartilaginous tissue and the opposite surface consists of osseous tissue. Group II is drawn to a biological joint replacement comprising two joint constructs as described in Group I. Applicant traverses that Groups I and II should be rejoined because Group II is not independent from Group I and that a search for both Groups would not impose a serious burden on the Office.

The examiner agrees. Group II is thereby rejoined to elected Group I.

Applicant also traverses that Group III, which is drawn to a process for the production of a biological joint construct, should be rejoined with the product of Group I because the product of Group I is not well known in the art. Applicant asserts that U.S. '272 (Mears et al.) does not teach or suggest the product of Group I, and that unity of invention is therefore not lacking. Applicant requests rejoinder of Group III to Group I since Group III is drawn to a method of producing the special technical feature, i.e. Group I.

The examiner disagrees. Upon closer reading of the claims of Group III, the examiner has determined that the process steps described in claim 45 and its dependent claims do not necessarily produce the product of Group I. In the joint construct of Group I, one surface consists of cartilaginous tissue and the opposite surface consists of osseous tissue. The construct of Group I cannot, therefore, be interpreted as having any other form. For example, Group I cannot be drawn to a construct in which the osseous cells are grown on top of, or cocultured with, the cartilaginous cells. The construct of Group I necessarily has two distinctly populated sides or ends.

The process of Group III, however, is drawn to populating a carrier material with osteoblasts, populating the material with chondrocytes, connecting the resulting cells, and culturing the construct in vitro. Even in dependent claims of Group III, the process steps do not require that one side or end of the construct be populated exclusively with osseous tissue and the other exclusively with cartilaginous tissue. The process steps of Group III could produce a construct comprising a carrier material covered with a mixture of osseous and cartilaginous cells in any configuration, e.g. random scattering. Group III, therefore, is not drawn to a method of making the product of Group I.

The requirement is still deemed proper and is therefore made FINAL. Prosecution will proceed at this time on claims 36-44. Claims 45-66 are withdrawn from consideration.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

It is noted that the amended claims are numbered correctly. Numerous claims, however, still depend from cancelled claims. Claims 37-44 should be amended to correct claim dependency.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recites a biological joint construct that "is **designed as** an individual preformed construct." Claim 41 recites a biological joint construct that "is **designed as** an osteochondral cylinder." It is unclear whether these "designed as" descriptions are limitations on the structure of the construct or whether they are simply statements of intended use. The claims should be amended to remove the words "designed as." Additionally, osteochondral cylinders are defined in the art as portions of bone that are

transplanted from one part of a patient's body to another, which is inconsistent with the claims in light of the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 37, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. '050 (1991, reference A) in light of Thomas (1997, Taber's Cyclopedic Medical Dictionary, 18th Ed.; reference U) AND Boden (1999, Clin. Orthop. 376: S84-S94; reference V). The claims are drawn to a biological joint construct produced at least partly in vitro, comprising at least one biocompatible carrier material, cartilaginous tissue, and osseous tissue, such that one surface of said construct consists of cartilaginous tissue and the opposite surface consists of osseous tissue. In some dependent claims, the construct's size and shape match the portion of the joint to be replaced.

U.S. '050 teaches biological joint constructs produced in vitro, comprising a biocompatible carrier material (e.g. fibrinogen-based adhesive matrix) and chondrocytes, which are implanted into defective bones (Examples 1-3 and The Process). Additionally, the constructs of U.S. '050 can be produced in any shape,

including cylinders (column 4, line 68) and the precise shape of the damaged area (column 5, lines 3-4). Thomas is cited as evidence that synovial joints comprise two bones, each with a layer of articular cartilage coating the epiphyseal end (p. 1035) and that bone tissue comprises endothelial cells, i.e. blood vessels (p.249). Boden is cited as evidence that bone tissue contains growth factors (p.3, e.g.).

The claims currently read on any biological joint construct that, upon implantation, integrates into a bone and leads to the formation of layers of cartilage on the bone's end. This interpretation of the claims is consistent with the specification, drawings and examples. Claims 36, 37, 40 and 41 recite three requirements which render them nonpatentable: (a) the construct must be produced at least partly *in vitro*, meaning that the layers may form at least partly *in vivo*; (b) the joint (cartilaginous) side contacts another joint part, which is true of the epiphyses of all bones; and (c) the anchor (osseous) side firmly joins the cartilaginous side to the bone shaft. As the constructs of U.S. '050 are prepared partly *in vitro*, can be used to add articular cartilage to epiphyseal tips, and connect to the intact bone shaft, they anticipate the invention of claims 36, 37, 40 and 41.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '050, Thomas and Boden as applied to claims 36, 37, 40 and 41 above, and further in view of U.S. '296. The claims are drawn to a biological joint construct in which at least one cylindrical peg connects the construct to the bone shaft, and to a joint

replacement which comprises two joint constructs that contact each other on their joint (cartilaginous) sides. U.S. '050 does not teach a construct with a peg or a two-construct joint replacement.

U.S. '296 teaches a joint construct that is anchored into the bone shaft with a cylindrical peg (stems **16** and **19** in Figures 1-4). U.S. '296 also teaches a joint prosthesis comprising two components that engage with each other (Figures 1-4).

The skilled artisan would have had a reasonable expectation of success in adding the cylindrical peg of U.S. '296 to the joint construct of U.S. '050 because the construct of U.S. '050 can be constructed in any shape and size (column 5, lines 3-6). The skilled artisan would have been motivated to use the peg of U.S. '296 in the construct of U.S. '050 for the expected benefit that a peg articulated into the bone shaft would produce a more secure fit than would two flat ends touching.

It would therefore have been obvious to a person of ordinary skill in the art to make the construct of U.S. '050 with the peg of U.S. '296 because the construct of U.S. '050 can be of any shape and size.

The skilled artisan would also have had a reasonable expectation of success in making a joint replacement comprising two constructs of U.S. '050 because the construct of U.S. '050 can be constructed in any shape and size (column 5, lines 3-6). The skilled artisan would have been motivated to make two of the constructs of U.S. '050 as in the joint replacement of U.S. '296 because U.S. '296 discloses that two-member joint replacements (i.e., those consisting of two portions, each of which covers one epiphyseal end in the joint, but which are not necessarily connected into one

apparatus) present a problem in that the positioning of the two elements relative to each other so that they function properly is difficult (column 1, lines 32-34).

It would therefore have been obvious to a person of ordinary skill in the art to make a joint replacement using two of the constructs of U.S. '050 because U.S. '296 discloses that single-element joint replacements are more likely to function well than two-element joint replacements. Additionally, diseases such as rheumatoid arthritis often require the replacement of an entire joint, not just the end of one bone.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 39, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '050, Thomas, Boden and U.S. '296 as applied to claims 36-38 and 40-42, above, and further in view of U.S. '660 (1981, reference C) and Dunn et al. (1995, J. Biomed. Mater. Res. 29: 1363; reference W). The claims are drawn to biological joint constructs and replacements as described above, with the further limitation that the parts are connected together with ligamentous material. In some dependent claims, the joint replacement has a joint capsule. A joint capsule replacement can be constructed from the same materials as a ligament replacement (p.4 of specification). U.S. '050 and U.S. '296 do not teach joint constructs or replacements with ligaments or joint capsules.

U.S. '660 teaches a prosthetic ligament device comprising an elastic synthetic woven material, the device being securable to bones by use of bone screws (claim 1 and Figures). Dunn et al. teach a ligament analog prepared by seeding collagen

scaffolds with fibroblasts that approximates the structure and strength of native ligament tissue. The artificial ligament of Dunn et al. remains viable after implantation into a joint.

A person of ordinary skill in the art would have had a reasonable expectation of success in connecting the parts of the joint replacements of U.S. '050 and U.S. '296 with the artificial ligaments of U.S. '660 and Dunn et al. because the artificial ligaments are disclosed as having properties similar to native ligament tissue. The skilled artisan would have been motivated to connect the apparatus parts of U.S. '050 and U.S. '296 with the ligament constructs of U.S. '660 and Dunn et al. for the expected benefit of strengthening the replaced joint. The artificial ligament of U.S. '660 in particular is disclosed as having elastic properties closely approximating natural ligament tissue (Figures 2 and 3), so joining the joint replacement elements with the ligament of U.S. '660 would more closely simulate a natural joint (see Abstract).

It would therefore have been obvious to a person of ordinary skill in the art to connect the joint constructs of U.S. '050 and U.S. '296 with ligament constructs in order to stabilize the replacement joint and to simulate more closely the natural properties of the joint.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn, can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

SANDRA E. SAUCIER
PRIMARY EXAMINER